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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,745	06/27/2003	Peter Gluckman	704652-9001	5345

7590 08/29/2006

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,745	GLUCKMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-26,28-38,64 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-26,28-38,64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The amendments to the title, specification, and claims filed August 4, 2006 are not in compliance with the reissue amendment rules set forth in 37 CFR 1.173(b) and (d). Note that the status identifiers and the amendment markings are different for reissue applications than for regular applications. The amendment rules set forth in 37 CFR 1.121 do not apply to reissue applications. Before this application can be allowed, all changes intended to be made relative to the patent must be submitted in proper format.

2. The maintenance fees due at 3.5 years and 7.5 years after the issue date of U.S. Patent No. 5,714,460 have been paid, and therefore the reissue procedures are available for this patent.

This reissue application was filed within two months of the mailing date of the final judgment of interference 104,553, and therefore the reissue procedures are available for this patent.

3. This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172*(a). The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b).

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

Papers attempting to establish the consent of assignee to the reissue were filed on November 1, 2004. However, the papers are contradictory. One paper, signed by Timothy R. Schwartz, PhD., states that Genentech, Inc. is the owner of the entire right, title and interest in

and to U.S. Patent No. 5,714,460. A second paper, signed by Paulina Lucrynska (sp.?), states that NeuronZ Limited is the owner of the entire right, title and interest in and to U.S. Patent No. 5,714,460. Two separate legal entitles cannot each be the owner of the entire right, title and interest in a single U.S. patent. Further, according to the assignment records of the U.S. Patent and Trademark Office, NeuronZ LTD is the only assignee of record for U.S. Patent No. 5,714,460. Correction is required.

4. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,583,114 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

5. It should be noted that there is no claim for priority under 35 U.S.C. 119(a)-(d) present in this reissue application. A claim for the benefit of an earlier filing date in a foreign country under 35 U.S.C. 119(a)-(d) must be made in a reissue application, even though such a claim was previously made in the application for the original patent to be reissued. See MPEP 1417, which also outlines the procedures for claiming priority under 35 U.S.C. 119(a)-(d) in a reissue application.

6. The reissue oath/declaration filed with this application is defective because it fails to contain a statement that all errors which are being corrected in the reissue application up to the time of filing of the oath/declaration arose without any deceptive intention on the part of the applicant. See 37 CFR 1.175 and MPEP § 1414.

Claims 16-26, 28-38, 64, and 65 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175. The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

7. The disclosure is objected to because of the following informalities: The amended claim for priority in the paragraph beginning at column 1, line 3, of the specification is objected to because the issue date of U.S. Patent No. 5,714,460 is incorrect. The correct issue date is February 3, 1998. Appropriate correction is required.

8. Claims 16-26, 28-38, 64, and 65 are rejected under 35 U.S.C. 251 as being based upon new matter added to the patent for which reissue is sought. The added material which is not supported by the prior patent is as follows: In the amendment filed August 4, 2006 to the paragraph beginning at column 1, line 3, of the specification, an incorporation by reference to New Zealand Patent Application 239211 has been included. However, this reissue application was not originally filed with such an incorporation by reference statement, and the submission of a new incorporation by reference statement after the filing date of this reissue application is new matter. See MPEP 201.11(III), first paragraph.

9. The amendment filed August 4, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

supported by the original disclosure is as follows: In the amendment to the paragraph beginning at column 1, line 3, of the specification, an incorporation by reference to New Zealand Patent Application 239211 has been included. However, this reissue application was not originally filed with such an incorporation by reference statement, and the submission of a new incorporation by reference statement after the filing date of this reissue application is new matter. See MPEP 201.11(III), first paragraph. Applicant is required to cancel the new matter in the reply to this Office Action.

10. Claims 16-25 and 28-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended to recite that the CNS injury predominantly affects glia. The meaning of the term "predominantly" as used in the claim context is not clear. As indicated in section [9] of the Decision On Motions, "Glia support the activity of neurons, regulate the environment of neurons, and insulate neurons". It is not seen how glia can be damaged without sooner or later injuring the neurons which are supported, regulated, and insulated by the glia. Further, Applicants claim treating glial cells which are damaged by, e.g., ischemic injury, hypoxic injury, asphyxia injury, and traumatic brain injury. These types of injuries result in generalized damage to the CNS. Because glia cells and neuronal cells are not physically separated from one another, these types of injuries will necessarily result in damage to both glial and neuronal cells. Again, it is not clear how these types of injuries could be said to result in damage "predominantly" to glia cells. The basis for characterizing an injury as affecting "predominantly" glia is not understood (other than for specific diseases such

as multiple sclerosis which are recognized as targeting glia cells), and accordingly the scope of the claims can not reasonably be determined.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 16-18, 23-26, 28-30, and 35-38 are rejected under 35 U.S.C. 103 as being estopped on the merits by final judgment in Interference No. 104,533. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. The interference count does not recite that the CNS injury predominately affects glia. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to

treat glial cells damaged by CNS injury which predominantly affects glia, because the interference count specifically recites that injured glia cells are to be treated, and the lack of injury to other types of cells would not have been expected to interfere with the ability of IGF-1 and its analogues to treat injured glia cells. With respect to instant claims 17, 23, 29, and 35, these claims recite the same limitation as is recited in claims 3 and 4 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 27-29 of the Decision On Motions). Accordingly, claims 17, 23, 29, and 35 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. With respect to instant claims 18 and 30, these claims recite the same limitation as is recited in claim 2 of the '460 patent, which was designated as corresponding to the count. Gluckman did not file any motion in the interference contesting the designation of this claim as corresponding to the count. Accordingly, claims 18 and 30 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. With respect to claims 24-26 and 36-38, these claims recite the same or broader limitations as are recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Accordingly, claims 24-26 and 36-38 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in the interference as

indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over the lost count.

13. Claims 16, 24-26, 28, and 36-38 are rejected under 35 U.S.C. 102(g) and/or 103 as being estopped on the merits by final judgment in Interference No. 104,533. In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. With respect to claims 16, 24-26, 28, and 36-38, these claims recite the same or broader limitations as is recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision On Motions). Further, Applicants' specification at column 1, lines 44-46, acknowledges that multiple sclerosis is a disease of the CNS which causes the loss of oligodendrocytes (which are a type of glia cells). This section of Applicants' specification is quoted in section [19] of the Decision On Motions. See also section [93] of the Decision On Motions. Accordingly, the count, which suggests treating glial cells which are injured by multiple sclerosis, also suggests the broader limitation of treating glial cells damaged by CNS injury which predominantly affects glia. Claims 16, 24-26, 28, and 36-38 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled "Notice Under 37 C.F.R. §1.178(b)" filed June 27, 2003, Applicants refer to footnote 17 of the Decision On Motions in

the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over (or even anticipated by) the lost count.

14. Applicant's arguments filed August 4, 2006 have been fully considered but they are not persuasive.

The objection under 37 CFR 1.172(a) based upon non-establishment of ownership interest in the patent for which reissue is being requested is maintained. While the examiner does not disagree with the statutory citations and legal analyses made in Applicants' discussion of this issue, they do not address the issues raised in the objection. The separate ownership statements contradict one another, and the statement by Genentech, Inc. contradicts Office assignment records. There is no indication in any of the papers filed that Genentech, Inc. and NeuronZ Limited "together" own the entire right, title and interest in U.S. Patent No. 5,714,460, and this type of ownership would also contradict Office assignment records.

With respect to the claim for priority under 35 U.S.C. 119(a)-(d), the unexecuted reissue declaration filed August 4, 2006 contains an acceptable claim for priority. However, the executed copy of the declaration has not been received as of the time it became necessary to prepare this Office action.

The objection to the title of the invention has been overcome by Applicants' amendment, although, as noted above, Applicants will have to re-submit the title amendment in proper amendment format.

The objection and rejection of the reissue declaration filed with this application are maintained. An executed copy of the reissue declaration filed August 4, 2006 has not been received as of the time it became necessary to prepare this Office action. However, the executed copy will not satisfy the requirement made in the objection and rejection. The statement as to deceptive intention which is present in the unexecuted copy of the reissue declaration recites "on the part of the application" rather than "on the part of the applicants".

Certain of Applicants' claims remain rejected on the basis of interference estoppel. The basis of the first rejection is that, because the interference count recites treating glia cells damaged from CNS injury, the interference count suggests treating glia cells damaged from CNS injury in which the predominant effect is to glia cells. The interference count suggests treating injured glia cells even when there is a relative lack of injury to other types of cells. The basis of the second rejection is that during the interference, claims drawn to the treatment of glial cells injured by multiple sclerosis were designated as corresponding to the count. Therefore, those of the current claims which recite or embrace treatment of glial cells injured by multiple sclerosis should also be considered to correspond to the count and are at least suggested thereby. The new claim limitation that the CNS injury predominantly affects glia cells does not provide an additional basis for distinguishing claims drawn to the treatment of glial cells inured by multiple sclerosis, because the new claim limitation is merely a known and defining characteristic of multiple sclerosis. Applicants' arguments do not contain any reasons as to why the instant claims are patentably distinct over the interference count.

The prior art rejections based upon the WO Patent Application 90/14838 are withdrawn in view of the new claim limitation "wherein said CNS injury predominately affects glia". The

WO Patent Application '838 does not teach such types of injuries, and because the focus of the WO Patent Application '838 is upon the treatment of injury to neuronal cells, the reference does not suggest the treatment of injuries which predominantly affect glia, i.e. non-neuronal cells.

The prior art rejection based upon the Gluckman et al article (Biochem. Biophys. Res. Comm. vol. 182, pages 593-599) is withdrawn in view of the new claim limitation "wherein said CNS injury predominately affects glia". The Gluckman et al article does not teach such types of injuries, and because the Gluckman et al article is silent as to the effects of the injuries or the treatments on glia, the reference does not provide any motivation or suggestion to treat injuries which predominantly affect glia.

The prior art rejection based upon Cohen et al (U.S. Patent No. 5,219,837) is withdrawn in view of the new claim limitation requiring the analog to be a naturally-occurring analog, IGF-2, or des 103 IGF-1. The peptides taught by Cohen et al do not meet or suggest this limited class of IGF-1 analogs.

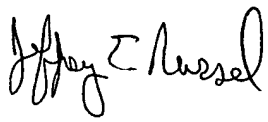
15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

August 23, 2006